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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/502,458
Filing Date: July 22, 2004
Appellant(s): BADYAL ET AL.

Fish & Richardson P.C.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 18 June 2007 appealing from the Office action mailed 28 September 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

WO 99/42154 A1	WARBY	08-1999
WO 98/58117 A1	BADYAL et al.	12-1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 3-7, and 9-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Warby (WO 99/42154 A1) in view of Badyal et al. (WO 98/58117 A1).

Warby teaches an apparatus for dispensing a medicament wherein one or more of the internal surfaces of the apparatus are coated with cold plasma polymerized monomers (page 2, line 33-page 3, line 5). The coating may be applied to the powder storage chamber (i.e. can), stem, valve (i.e. actuator), seals, and other devices such as non-pressurized actuators (page 8, line 10-page 9, line 11). Suitable monomers include fluorinated monomers, such as perfluorocyclohexane, perfluorohexane, tetrafluoroethylene, trifluoroethylene, vinylidene fluoride, vinyl fluoride, and fluorinated ethylene/propylene (page 7, lines 14-26).

Warby does not teach the use of a fluorinated acrylate.

Badyal et al. teach an oil and water repellent coating designed to prevent or inhibit soiling (page 1, lines 6-12). The degree of repellency is a function of the number and length of fluorocarbon groups (page 1, lines 19-23). The coating may be applied to biomedical devices (page 10, lines 9-14). The coating may be formed from a fluoroacrylates, such as 1H, 1H, 2H, 2H heptadecafluorodecyl acrylate (see Example 3).

It would be obvious to one skilled in the art to use the monomer of Badyal as the fluorinated monomer in the coating of Warby because the coating of Badyal et al. serves the same purpose as that of Warby (i.e. a repellent coating for biomedical devices) and it is *prima facie* obvious to select a known material based on its suitability for its intended use. See MPEP 2144.07. Moreover, because the specific fluoroacrylate used by Badyal et al., 1H, 1H, 2H, 2H

heptadecafluorodecyl acrylate, has a longer fluorinated chain than the specific monomers disclosed in Warby, one skilled in the art would be further motivated to use the monomer of Badyal et al. to improve the repellency since Badyal et al. teach that the degree of repellency is a function of the length of the fluorocarbon groups.

Regarding claims 7 and 13, the particular drug for which the device is intended to be used is a limitation drawn to the intended use of the device. Since, it has been held that a recitation with respect to the manner in which a claimed product is intended to be employed does not differentiate the claimed product from a prior art product satisfying the claimed structural limitations, the article of Warby reads on the device of instant claim 7. See MPEP 2114.

(10) Response to Argument

In response to the appellants' arguments that there is no motivating disclosure in the references of record that would have led one of ordinary skill in the art to look to Badyal when considering modifications to the coating of Warby, the examiner notes that the rationale to modify or combine the prior art does not have to be expressly stated in the prior art. As outlined in MPEP 2144, the courts have established that the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. In the instant case, one skilled in the art would be motivated to use the coating of Badyal et al. in place of the coating of Warby because both coatings are in the same field of endeavor (fluorinated, hydrophobic polymers applied as coatings by cold plasma on biomedical devices) and serve the same function (a hydrophobic coating: page 7, lines 5-13 of Warby and page 1, lines 3-5 of Badyal et al.) and the courts have held that the selection of a known material

(e.g. the hydrophobic, fluorinated polymer of Badyal et al.) based on its suitability for its intended use (a hydrophobic coating) supports a *prima facie* obviousness determination. See MPEP 2144.07. Moreover, it is noted that the final rejection provides additional motivation that is based directly on the teachings of Badyal et al. - namely, that monomers with longer fluorinated groups provide greater water repellency, i.e. a greater hydrophobic characteristic. The monomer used in Example 3 of Badyal et al., 1H,1H,2H,2H-heptadecafluorodecyl acrylate, has longer fluorinated groups than any of the fluorinated monomers taught by Warby. Since the coating of Warby is intended to be hydrophobic (see page 7, lines 5-13) and Badyal et al. explicitly teach that the degree of repellency is a function of the length of the fluorocarbon groups, the second rationale for combining Warby and Badyal et al. is derived directly from Badyal et al.

In response to the appellants' arguments that one skilled in the art would not have had a reasonable expectation of success, the examiner notes that the coating of Badyal et al. is described as water-repellent (see page 1, lines 3-5) while Warby states that the deposition of active drugs is reduced through the application of a hydrophobic treatment due, at least in part, to its waterproof characteristics (page 7, lines 5-13). Thus, one skilled in the art should have a reasonable expectation of success since it appears that it is the hydrophobic nature of the coating which inhibits the deposition of drugs.

In response to the appellants' arguments that the purposes of the coatings of Warby and Badyal et al. do not serve the same purpose as the coating of Warby is intended to inhibit the

deposition of a drug on the surface of a drug delivery device while that of Badyal et al. is designed to impart oil and water repellency, particularly to a fabric, the examiner contends that Warby explicitly call for the application of a hydrophobic (i.e. water repellant) coating and teach that it is the very hydrophobic nature of such a coating that prevents the adherence of the drug to the drug delivery device. It is also noted that Badyal et al. is directed broadly to oil and water repellent coatings that are suitable for application to "a wide variety of surfaces" including metal, glass, ceramics, paper, and polymers and not just fabrics, with biomedical devices explicitly cited as a suitable application for their coating (see page 1, lines 3-12 and page 10, lines 9-14). It should also be noted that, contrary to the appellants' assertion, Badyal et al. do illustrate embodiments wherein their coating is applied to a substrate other than a fabric as both Examples 1 and 3 utilize a glass as the substrate on which the coating is applied.

In response to the appellants' argument that one skilled in the art would more like have simply extended the length of the monomers used by Warby as opposed to replacing the monomers of Warby monomers with those disclosed in Badyal et al., which include polar moieties such as esters and amides, the examiner notes that the comparative data of Badyal et al. illustrates that the fluorinated acrylate coating of Badyal et al. actually exhibits a *greater* hydrophobic nature than a coating formed from a fluorinated alkene monomer. Consider Examples 2 and 4 of Badyal et al. Example 2 (starting on page 15) is directed to a pulsed plasma coating of 1H,1H,2H-perfluoro-1-dodecene while Example 4 (starting on page 18) is directed to a pulsed plasma coating of 1H,1H,2H,2H-heptadecafluorodecyl acrylate. The monomer of Example 2 is a fluorinated hydrocarbon monomer having a perfluorinated side group of 10

carbon atoms, that is more than twice as long as that of the preferred monomer of Warby, perfluorohexane, which has a perfluorinated side group of 4 carbon atoms in length. The resulting fluorinated acrylate coating of Example 4 has a water repellency of 10 (see the upper-rightmost entry in the table at the bottom of page 18 corresponding to a pulsed plasma deposition not subjected to benzotrifluoride Soxhlet extraction). By contrast the water repellency reported for Example 2 is 9. That is, based on the showings in Badyal et al., one skilled in the art desiring a coating that is more hydrophobic (and therefore less susceptible to drug deposition) would be motivated to use the fluorinated acrylate taught by Badyal et al. (particularly the monomer illustrated in Example 4) rather than simply extend the length of the fluorocarbon group in the monomer of Warby as Badyal et al. demonstrate that a coating formed from the fluorinated acrylate monomer of Example 4 exhibits a greater hydrophobic nature than a similar coating formed from a fluorinated hydrocarbon having a fluorinated group that is larger than any of the monomers taught by Warby.

Moreover, the appellants' allegation that the comparative data of Example 2 and 4 pertains specifically to the relative oil and water repellency of coated cotton and not the relative hydrophobicity that would be exhibited by the surface of a drug delivery device appears to be speculation that is not supported by an evidence or reasoning. While Badyal et al. indicate that factors such as fabric construction and fibre type influence stain resistance, Badyal et al. state that their repellency tests can be used to compare various finishes (page 15, lines 20-25). Therefore, while the tests might not indicate an absolute measure of water repellency, one skilled in the art would expect the tests to yield insight into the relative hydrophobicity of the difference finishes. It should be noted that both Examples 2 and 4 use the same substrate and thus one

skilled in the art would expect the resulting differences in water repellency to be related to differences in the coatings and not a function of the substrate used.

Finally, in response to the appellants' argument that there is simply no reason why the artisan would have been motivated to look for other hydrophobic treatments when Warby indicates that his coating provides good results, the examiner notes that patents and other prior art references typically do not tout their deficiencies.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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